Amendments to the Claims

This listing of claims replaces all prior versions, and listings, of claims in the above-identified application:

1-88. (Cancelled)

89. (New) A method of tuning the delivery of an active agent from an implantable medical device to a subject at a target diffusivity, the method comprising:

receiving an implantable medical device comprising an active agent delivery system, wherein the active agent delivery system comprises an active agent and a miscible polymer blend, wherein the active agent delivery system is formed by a method comprising:

receiving a hydrophobic active agent having a molecular weight of no greater than about 1200 g/mol;

receiving a first polymer;

receiving a second polymer selected to be miscible with the first polymer to form a miscible polymer blend that controls the delivery of the active agent;

wherein at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

wherein each of the first polymer and the second miscible polymer has at least one solubility parameter, and the difference between at least one solubility parameter of each of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$;

wherein the active agent has a solubility parameter and the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$;

and further wherein each of the solubility parameters is independently determined by at least one method selected from measuring, obtaining the solubility parameter from a reference publication, taking an average of

calculations performed using the Hoy Method and the Hoftyzer-van Krevelen Method, and calculating by computer simulation; and

combining the first and second polymers in amounts sufficient to form a miscible polymer blend that controls the delivery of the active agent at a predetermined amount over a period of time;

wherein:

the swellability of the miscible polymer blend is no greater than 10% by volume; and

the molar average solubility parameter of the miscible polymer blend is no greater than 25 $J^{1/2}/cm^{3/2}$;

and further wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polyvinyl homopolymer or copolymer selected from the group consisting of a polyvinyl alkylate homopolymer or copolymer, a polyvinyl alkyl ether homopolymer or copolymer, a polyvinyl acetal homopolymer or copolymer, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and a second miscible polymer that is not a hydrophobic cellulose ester; wherein the second miscible polymer is selected from the group consisting of a polycarbonate, a polysulfone, a polyurethane, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a poly(vinyl ester), a poly(vinyl ether), a polyacrylate, a poly(methyl acrylate), a polymethacrylate, a poly(methyl methacrylate), and combinations thereof; or

the miscible polymer blend comprises a poly(ethylene-co-(meth)acrylate) and a second miscible polymer not including

poly(ethylene vinyl acetate); wherein the second miscible polymer is selected from the group consisting of a poly(vinyl alkylate) homopolymer or copolymer, a poly(vinyl alkyl ether) homopolymer or copolymer, a poly(vinyl acetal) homopolymer or copolymer, a poly(alkyl and/or aryl methacrylate) homopolymer or copolymer, a poly(alkyl and/or aryl acrylate) homopolymer or copolymer, and combinations thereof; and

contacting the implantable medical device comprising the active agent delivery system with a bodily fluid, organ, or tissue of a subject to deliver the active agent at a predetermined amount over a period of time, which is not controlled by porosity in the miscible polymer blend.

90. (New) The method of claim 89 wherein the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polyvinyl homopolymer or copolymer selected from the group consisting of a polyvinyl alkylate homopolymer or copolymer, a polyvinyl alkyl ether homopolymer or copolymer, a polyvinyl acetal homopolymer or copolymer, and combinations thereof.

91. (New) The method of claim 89 wherein the miscible polymer blend comprises a polyurethane and a second miscible polymer that is not a hydrophobic cellulose ester; wherein the second miscible polymer is selected from the group consisting of a polycarbonate, a polysulfone, a polyurethane, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a poly(vinyl ester), a poly(vinyl ether), a polyacrylate, a poly(methyl acrylate), a polymethacrylate, a poly(methyl methacrylate), and combinations thereof.

92. (New) The method of claim 89 wherein the miscible polymer blend comprises a poly(ethylene-co-(meth)acrylate) and a second miscible polymer not including poly(ethylene vinyl acetate); wherein the second miscible polymer is selected from the group consisting of a poly(vinyl alkylate) homopolymer or copolymer, a poly(vinyl alkyl ether) homopolymer or

copolymer, a poly(vinyl acetal) homopolymer or copolymer, a poly(alkyl and/or aryl methacrylate) homopolymer or copolymer, a poly(alkyl and/or aryl acrylate) homopolymer or copolymer, and combinations thereof.

93. (New) The method of claim 89 wherein the difference between at least one Tg of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

94. (New) The method of claim 89 wherein the active agent is incorporated within the miscible polymer blend.

95. (New) The method of claim 89 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

96. (New) The method of claim 95 wherein the active agent is incorporated within an inner matrix.

97. (New) The method of claim 89 wherein the active agent delivery system is in the form of microspheres, beads, rods, fibers, or other shaped objects.

98. (New) The method of claim 97 wherein the critical dimension of the object is no greater than about 10,000 microns.

99. (New) The method of claim 89 wherein the active agent delivery system is in the form of a film.

100. (New) The method of claim 99 wherein the thickness of the film is no greater than about 1000 microns.

101. (New) The method of claim 89 wherein the medical device is selected from the group consisting of a stent, stent graft, anastomotic connector, lead, guide wire, catheter, sensor, angioplasty balloon, wound drain, shunt, tubing, urethral insert, pellet, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lens.

102. (New) The method of claim 89 wherein delivery of the active agent occurs predominantly under permeation control.

103. (New) The method of claim 89 wherein receiving an implantable medical device comprises making the medical device comprising;

receiving a medical device comprising a surface; and

adhering the active agent delivery system to at least a portion of the surface.

104. (New) The method of claim 89 wherein the implantable medical device is a stent.

105. (New) A method of tuning the delivery of an active agent from an implantable medical device to a subject at a target diffusivity, the method comprising:

receiving an implantable medical device comprising an active agent delivery system, wherein the active agent delivery system comprises an active agent and a miscible polymer blend, wherein the active agent delivery system is formed by a method comprising:

receiving a hydrophilic active agent having a molecular weight of no greater than about 1200 g/mol;

receiving a first polymer;

receiving a second polymer selected to be miscible with the first polymer to form a miscible polymer blend that controls the delivery of the active agent;

wherein at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

wherein each of the first polymer and the second miscible polymer has at least one solubility parameter, and the difference between at least one solubility parameter of each of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$;

wherein the active agent has a solubility parameter and the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$;

and further wherein each of the solubility parameters is independently determined by at least one method selected from measuring, obtaining the solubility parameter from a reference publication, taking an average of calculations performed using the Hoy Method and the Hoftyzer-van Krevelen Method, and calculating by computer simulation; and

combining the first and second polymers in amounts sufficient to form a miscible polymer blend that controls the delivery of the active agent at a predetermined amount over a period of time;

wherein:

the swellability of the miscible polymer blend is no greater than 10% by volume; and

the molar average solubility parameter of the miscible polymer blend is greater than 25 $J^{1/2}/cm^{3/2}$;

and further wherein:

the miscible polymer blend comprises miscible polymers selected from the group consisting of polyacrylonitriles, cyanoacrylates, methacrylonitriles, hydrophilic cellulosics, and combinations thereof; or

the miscible polymer blend comprises a polyurethane and at least one miscible hydrophilic polymer selected from the group consisting of a

polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; or

the miscible polymer blend comprises two hydrophobic polyurethanes as a cap coat in a reservoir system; and

contacting the implantable medical device comprising the active agent delivery system with a bodily fluid, organ, or tissue of a subject to deliver the active agent at a predetermined amount over a period of time, which is not controlled by porosity in the miscible polymer blend.

106. (New) The method of claim 105 wherein the miscible polymer blend comprises a polyurethane and at least one miscible hydrophilic polymer selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof.

107. (New) The method of claim 106 wherein the miscible polymer blend comprises two hydrophobic polyurethanes as a cap coat in a reservoir system.

108. (New) The method of claim 105 wherein the difference between at least one Tg of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

109. (New) The method of claim 105 wherein the active agent is incorporated within the miscible polymer blend.

110. (New) The method of claim 105 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

111. (New) The method of claim 110 wherein the active agent is incorporated within an inner matrix.

112. (New) The method of claim 105 wherein the active agent delivery system is in the form of microspheres, beads, rods, fibers, or other shaped objects.

113. (New) The method of claim 112 wherein the critical dimension of the object is no greater than about 10,000 microns.

114. (New) The method of claim 105 wherein the active agent delivery system is in the form of a film.

115. (New) The method of claim 114 wherein the thickness of the film is no greater than about 1000 microns.

116. (New) The method of claim 105 wherein the medical device is selected from the group consisting of a stent, stent graft, anastomotic connector, lead, guide wire, catheter, sensor, angioplasty balloon, wound drain, shunt, tubing, urethral insert, pellet, pump, vascular graft,

valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lens.

117. (New) The method of claim 105 wherein delivery of the active agent occurs predominantly under permeation control.

118. (New) The method of claim 105 wherein receiving an implantable medical device comprises making the medical device comprising;

receiving a medical device comprising a surface; and

adhering the active agent delivery system to at least a portion of the surface.

119. (New) The method of claim 105 wherein the implantable medical device is a stent.

120. (New) A method of tuning the delivery of an active agent from an implantable medical device to a subject at a target diffusivity, the method comprising:

receiving an implantable medical device comprising an active agent delivery system, wherein the active agent delivery system comprises an active agent and a miscible polymer blend, wherein the active agent delivery system is formed by a method comprising:

receiving a hydrophobic active agent having a molecular weight of greater than about 1200 g/mol;

receiving a first polymer;

receiving a second polymer selected to be miscible with the first polymer to form a miscible polymer blend that controls the delivery of the active agent;

wherein at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

wherein each of the first polymer and the second miscible polymer has at least one solubility parameter, and the difference between at least one solubility parameter of each of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$;

wherein the active agent has a solubility parameter and the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$;

and further wherein each of the solubility parameters is independently determined by at least one method selected from measuring, obtaining the solubility parameter from a reference publication, taking an average of calculations performed using the Hoy Method and the Hoftyzer-van Krevelen Method, and calculating by computer simulation; and

combining the first and second polymers in amounts sufficient to form a miscible polymer blend that controls the delivery of the active agent at a predetermined amount over a period of time;

wherein:

the swellability of the miscible polymer blend is greater than 10% by volume; and

the molar average solubility parameter of the miscible polymer blend is no greater than 25 $J^{1/2}/cm^{3/2}$;

and further wherein:

the miscible polymer blend comprises at least one hydrophobic cellulose derivative and at least one miscible polymer selected from the group consisting of polypropylene, polystyrene, poly(vinyl chloride), poly(vinyl bromide), poly(vinylidene chloride), poly(chloro trifluoroethylene), poly(vinyl alcohol), poly(vinyl acetate), poly(vinyl propionate), poly(methyl acylate), poly(ethyl acrylate), poly(propyl acrylate), poly(butyl acrylate), poly(isobutyl acrylate), poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate),

poly(isobutyl methacrylate), poly(tert-butyl methacrylate), poly(benzyl methacrylate), poly(ethoxyethyl methacrylate), polyacrylonitrile, polymethacrylonitrile, poly(alpha-cyanomethyl acrylate), polychloroprene, polyformaldehyde, poly(tetramethylene oxide), polyepichlorohydrin, poly(ethylene sulphide), poly(styrene sulphide), poly(ethylene terephthalate), poly(8-aminocaprylic acid), poly(hexamethylene adipamide), polyurethane hard segment (MDI + BDO), poly(bisphenyl A carbonate), cellulose acetate butyrate, phenoxy, poly(vinyl pyrrolidone), poly(vinyl pyrrolidone)-co-poly(vinyl acetate), poly(ethylene oxide), and combinations thereof; and

contacting the implantable medical device comprising the active agent delivery system with a bodily fluid, organ, or tissue of a subject to deliver the active agent at a predetermined amount over a period of time, which is not controlled by porosity in the miscible polymer blend.

121. (New) The method of claim 120 wherein the difference between the swellabilities of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

122. (New) The method of claim 120 wherein the active agent is incorporated within the miscible polymer blend.

123. (New) The method of claim 120 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

124. (New) The method of claim 123 wherein the active agent is incorporated within an inner matrix.

125. (New) The method of claim 120 wherein the active agent is not heparin.

126. (New) The method of claim 120 wherein the active agent delivery system is in the form of microspheres, beads, rods, fibers, or other shaped objects.

127. (New) The method of claim 126 wherein the critical dimension of the object is no greater than about 10,000 microns.

128. (New) The method of claim 120 wherein the active agent delivery system is in the form of a film.

129. (New) The method of claim 128 wherein the thickness of the film is no greater than about 1000 microns.

130. (New) The method of claim 120 wherein the medical device is selected from the group consisting of a stent, stent graft, anastomotic connector, lead, guide wire, catheter, sensor, angioplasty balloon, wound drain, shunt, tubing, urethral insert, pellet, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lens.

131. (New) The method of claim 120 wherein delivery of the active agent occurs predominantly under permeation control.

132. (New) The method of claim 120 wherein receiving an implantable medical device comprises making the medical device comprising;

receiving a medical device comprising a surface; and

adhering the active agent delivery system to at least a portion of the surface.

133. (New) The method of claim 120 wherein the implantable medical device is a stent.

134. (New) A method of tuning the delivery of an active agent from an implantable medical device to a subject at a target diffusivity, the method comprising:

receiving an implantable medical device comprising an active agent delivery system, wherein the active agent delivery system comprises an active agent and a miscible polymer blend, wherein the active agent delivery system is formed by a method comprising:

receiving a hydrophilic active agent having a molecular weight of greater than about 1200 g/mol;

receiving a first polymer;

receiving a second polymer selected to be miscible with the first polymer to form a miscible polymer blend that controls the delivery of the active agent;

wherein at least one polymer has an active agent diffusivity higher than the target diffusivity and at least one polymer has an active agent diffusivity lower than the target diffusivity;

wherein each of the first polymer and the second miscible polymer has at least one solubility parameter, and the difference between at least one solubility parameter of each of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$;

wherein the active agent has a solubility parameter and the difference between the solubility parameter of the active agent and at least one solubility parameter of at least one of the polymers is no greater than about 3 $J^{1/2}/cm^{3/2}$;

and further wherein each of the solubility parameters is independently determined by at least one method selected from measuring, obtaining the solubility parameter from a reference publication, taking an average of calculations performed using the Hoy Method and the Hoftyzer-van Krevelen Method, and calculating by computer simulation; and

combining the first and second polymers in amounts sufficient to form a miscible polymer blend that controls the delivery of the active agent at a predetermined amount over a period of time;

wherein:

the swellability of the miscible polymer blend is greater than 10% by volume; and

the molar average solubility parameter of the miscible polymer blend is greater than 25 $J^{1/2}/cm^{3/2}$;

and further wherein:

the miscible polymer blend comprises at least one hydrophilic polymer and a second miscible polymer that is hydrophilic or hydrophobic; wherein the hydrophilic polymer is selected from the group consisting of a polyurethane, a polyvinyl alcohol, a poly(alkylene ether), a polyvinyl pyridine, a polyvinyl pyrrolidone, a polyacrylonitrile, a polyacrylamide, a polyvinyl pyrrolidone/polyvinyl acetate copolymer, a sulfonated polystyrene, a polyvinyl pyrrolidone/polystyrene copolymer, a polysaccharide, a xanthan, a hydrophilic cellulose derivative, a hyaluronic acid, a hydrophilic polyacrylate, a hydrophilic polymethacrylate, a DNA or analog thereof, an RNA or analog thereof, heparin, a chitosan, a polyethylene imine, a polyacrylamide, an amine-containing polymer, and combinations thereof; and the hydrophobic polymer is selected from the group consisting of a polyurethane, a polycarbonate, a polysulfone, a polyphenylene oxide, a polyimide, a polyamide, a polyester, a polyether, a polyketone, a polyepoxide, a styrene-acrylonitrile copolymer, a polyvinyl alkylate, a polyvinyl alkyl ether, a polyvinyl acetal, a hydrophobic cellulose derivative, and combinations thereof; and

contacting the implantable medical device comprising the active agent delivery system with a bodily fluid, organ, or tissue of a subject to deliver the active agent at a predetermined amount over a period of time, which is not controlled by porosity in the miscible polymer blend.

135. (New) The method of claim 134 wherein the difference between the swellabilities of at least two of the polymers corresponds to a range of diffusivities that includes the target diffusivity.

136. (New) The method of claim 134 wherein the active agent is incorporated within the miscible polymer blend.

137. (New) The method of claim 134 wherein the miscible polymer blend initially provides a barrier for permeation of the active agent.

138. (New) The method of claim 137 wherein the active agent is incorporated within an inner matrix.

139. (New) The method of claim 134 wherein the second miscible polymer is a hydrophobic polymer.

140. (New) The method of claim 134 wherein the second miscible polymer is a hydrophilic polymer.

141. (New) The method of claim 140 wherein the second miscible polymer is a hydrophilic polyurethane.

142. (New) The method of claim 134 wherein the active agent is not heparin.

143. (New) The method of claim 134 wherein the active agent delivery system is in the form of microspheres, beads, rods, fibers, or other shaped objects.

144. (New) The method of claim 143 wherein the critical dimension of the object is no greater than about 10,000 microns.

145. (New) The method of claim 134 wherein the active agent delivery system is in the form of a film.

146. (New) The method of claim 145 wherein the thickness of the film is no greater than about 1000 microns.

147. (New) The method of claim 134 wherein the medical device is selected from the group consisting of a stent, stent graft, anastomotic connector, lead, guide wire, catheter, sensor, angioplasty balloon, wound drain, shunt, tubing, urethral insert, pellet, pump, vascular graft, valve, pacemaker, orthopedic device, replacement device for nucleus pulposus, and intraocular lens.

148. (New) The method of claim 134 wherein delivery of the active agent occurs predominantly under permeation control.

149. (New) The method of claim 134 wherein receiving an implantable medical device comprises making the medical device comprising;

receiving a medical device comprising a surface; and

adhering the active agent delivery system to at least a portion of the surface.

150. (New) The method of claim 134 wherein the implantable medical device is a stent.